

alone: 3, other combination chemotherapy: 9 and 1 underwent reduced intensity allogeneic transplantation. Two pts were not fit to receive further treatment and had rapidly progressive disease (PD). Of the treated pts, 6 achieved CR (4 subsequently progressed), 5 PR and 7 had PD. Eleven pts remain alive (only 2 in CR) with PD accounting for all deaths. With a median follow-up of 31 months (m) post relapse for living pts, median PFS from the time of relapse post-ASCT was 5 m and OS was 34 m. No significant predictors of PFS could be identified. For OS, univariate analysis identified time to relapse (TTR; $p = 0.011$), performance status (PS; $p = 0.010$) and total IPI score ($p = 0.041$) as being statistically significant. Only TTR remained significant on the multivariate model. TTR less than 12 months portends a very poor outcome (2 year OS 0% compared to 62% form TTR >12 m; $p < 0.001$). **Conclusion:** Pts with MCL who relapse after ASCT do poorly, especially those relapsing within one year of ASCT. New therapeutic approaches incorporating maintenance therapy post-ASCT or the use of novel agents such as bortezomib or mTOR inhibitors should be explored in this group.

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FLUID RELATED COMPLICATIONS WITH FILGRASTIM (G-CSF) 10 MCG/KG ONCE DAILY VERSUS 5 MCG/KG TWICE DAILY IN AMYLOIDOSIS PATIENTS UNDERGOING PERIPHERAL BLOOD STEM CELL MOBILIZATION
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Background: High dose melphalan followed by peripheral blood stem cell (PBSC) transplantation is an established therapy for AL amyloidosis. One limitation is the frequent fluid related complications that occur during PBSC mobilization (Blood 2004;114:3a). The development of fluid related complications during mobilization predicts decreased survival after PBSC transplant (Blood 2005;106:3353). At Mayo Clinic, G-CSF 10 mcg/kg once daily was the standard until 2004. In attempt to reduce fluid related complications the practice changed to G-CSF 5 mcg/kg twice daily in July 2004. It is unknown if this change impacted the incidence of fluid related complications during PBSC mobilization. **Methods:** We conducted a retrospective evaluation of patients with amyloidosis undergoing PBSC mobilization at Mayo Clinic. Following IRB approval, patients were identified by reviewing the Mayo Clinic dysproteinemia data base and data extracted from the medical record. Forty-six patients from the once daily and 22 patients from the twice daily were excluded due to use of mobilization agents in addition to G-CSF, second mobilization, syngeneic transplant or consent refusal. A fluid related complication was defined as new peripheral

edema, pleural effusion or ascites, or initiation of supportive therapy (diuretics, albumin, or dopamine) to promote diuresis. **Results:** From 7/98 to 8/03, 123 patients received once daily G-CSF. From 7/04 to 8/07, 182 patients received twice daily G-CSF. Organ involvement was similar in both series; single organ (43% vs 36%; $p = 0.2$), two organs (38% vs 62%; $p = 0.5$) and 3 or more organs (22% vs 26%; $p = 0.5$). Most patients had either kidney involvement (65% vs 71%; $p = 0.2$) or heart involvement (51% vs 57%; $p = 0.3$). Baseline edema (61% vs 53% ($p = 0.06$)) and baseline diuretic use (58% vs 55% ($p = 0.7$)) was similar in both groups. Fluid related complications occurred with similar frequency regardless of administration schedule, 50% vs 51% ($p = 0.9$). Two patients in the once daily and 4 patients in the twice daily administration died prior to PBSC transplant. In patients that received a PBSC transplant, survival was similar at day 100; 88% vs 92% and one year; 83% vs 88% ($p = 0.6$). **Conclusion:** Changing from once daily to twice daily G-CSF administration in patients with amyloidosis did not impact the incidence of fluid related complications or mortality at day 100 or one year after PBSC transplant.

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PHASE II TRIAL EVALUATING APREPITANT (AP) FOR PREVENTION OF NAUSEA AND VOMITING SECONDARY TO HIGH-DOSE CYCLOPHOSPHAMIDE (CY) ADMINISTERED TO PATIENTS UNDERGOING AUTOLOGOUS (A) PERIPHERAL BLOOD PROGENITOR CELL (PBPC) MOBILIZATION
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Background: Adequate PBPC mobilization in the range of $2-5 \times 10^6$ CD34⁺ cells/kg body weight is a prerequisite for administration of high-dose chemotherapy and A-PBPC transplant. Cy and filgrastim combination provides a better PBPC yield as compared to filgrastim, which has a failure rate of 15–20%. In this setting, high-dose Cy is associated with significant nausea and vomiting. Ap is a new antiemetic that is a Neurokinin-1 receptor antagonist and may reduce the incidence of this side effect. We have conducted a phase II trial evaluating efficacy and safety of adding Ap to standard antiemetic combination of 5-HT3 antagonists and adjusted dose of corticosteroids. Primary objective of this study was the control of acute vomiting without the use of rescue medications at 24 hours post Cy. The data of the first interim report are presented. **Methods:** From May 2005 to May 2007, 22 pts were enrolled, four of whom are not evaluable for response. Three pts did not receive Ap; one withdrew consent after a single dose. All received Cy 4 gm/m² and filgrastim (10–16 mcg/kg/d) for stem cell mobilization. Granisetron 1 mg, dexamethasone 10 mg and Ap 125 mg was administered orally 1 hour before Cy followed by Ap 80 mg once daily \times 2 days. This study used Simon's optimal two-stage design constrained to fewer than 40 pts with 10% type I error and 85% statistical power. Ap is considered effective if it prevents nausea and vomiting in at least 65% of patients. Ap is judged ineffective if the rate of vomiting control was 45% or less. **Results:** Ten (55%) of 18 response-evaluable pts had no vomiting episodes and received no rescue medications during the first 24 hours following Cy. Of those who did not achieve the primary endpoint, four pts reported no vomiting episodes but received rescue medications. The other four pts had at least one vomiting episode and one received rescue anti-emetic. Ten pts had no delayed vomiting (25–120 hrs). Ten pts reported no nausea in 24 hours and five pts experienced mild nausea. Only 6/18 (33%) pts experienced moderate to severe delayed nausea (25–120 hrs). No toxicities related to Ap were noted for any patients. All pts had adequate mobilization of stem cells (median CD34⁺: 7.57×10^6 /kg) and proceeded to A-PBPC transplant. **Conclusion:** The results of this interim analysis justify continuation to stage 2 with enrollment of 17 more patients. Ap has potential to effectively control nausea and emesis in pts receiving high-dose Cy.

Comparison of Complications based on G-CSF Schedule of Administration

| | Once daily Filgrastim n = 123 N (%) | Twice daily Filgrastim n = 182 N (%) | p value |
|--|--|---|--------------|
| Fluid Complications | 63 (50) | 93 (51) | 0.9 |
| Hospitalization | 28 (23) | 24 (13) | 0.03 |
| Hospitalization related to fluid complication | 21 (17) | 10 (5) | 0.001 |
| Diuretic adjustment needed | 42 (34) | 89 (49) | 0.012 |
| Non-pharmacological intervention* | 10 (8) | 9 (5) | |
| Death prior to PBSC Transplant | 2 (1.6) | 4 (2.2) | |
| Patient did not undergo PBSC transplant | 9 (7.3) | 37 (20) | |

*Thoracentesis, Paracentesis, Hemodialysis, Pleurodesis, and Mechanical Ventilation.

Patients Characteristics (N = 18)

| | |
|------------------------------|----------------------------|
| Sex: Male/Female | 10/8 |
| Median Age (years) | 50 (range: 32–62) |
| Race | |
| Caucasians | 15 |
| African Americans | 3 |
| Diagnosis | |
| APL | 1 |
| HD | 1 |
| NHL | 8 |
| MM | 8 |
| Median CD34+ Cells/kg | 7.57 million |
| | (range: 2.93–76.16) |

APL: Acute Promyelocytic Leukemia, HD: Hodgkin Disease, MM: Multiple Myeloma, NHL: Non-Hodgkin Lymphoma.

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TOTAL BODY IRRADIATION BASED (TBI) VERSUS CHEMOTHERAPY-BASED-PREPARATIVE REGIMENS BEFORE AUTOLOGOUS STEM CELL TRANSPLANTS FOR NON-HODGKIN'S LYMPHOMA

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Objectives: The optimum high dose preparative regimen for non-Hodgkin lymphoma (NHL) patients undergoing autologous stem cell transplantation (ASCT) is unknown. We compared the radiation-based regimen of cyclophosphamide, etoposide and 12 Gy total body irradiation (CY/E/TBI) to carmustine, etoposide, cytarabine and melphalan (BEAM) in NHL patients who received ASCT. We investigated acute and long-term toxicities, disease free survival (DFS), overall survival (OS) of these two regimens. **Methods:** Historical cohort study was performed at a provincial cancer centre. Cause specific survival was determined with the Kaplan-Meier method. Survival between groups was compared using the log-rank test. **Results:** From Mar-1991 to Sep-2005, 79 patients received CY/E/TBI (n = 32) or BEAM (n = 47). Histology was indolent in 30 and aggressive in 49 patients. Cell source was bone marrow in six and 73 received peripheral blood progenitor cells. Prior to ASCT, ten patients were in complete remission, 47 had chemo-sensitive disease and 22 had chemo-resistant disease. There were only two cases of interstitial pneumonitis, with one in each preparative regimen group. There were six transplant related deaths; two in the BEAM group and four were in TBI group. The TBI based group has a higher mean mucositis score (p = 0.03). Five year DFS was 47% and 51% in the TBI and BEAM groups, respectively (p = 0.41). Five year OS was 50% and 64% for the TBI and BEAM based groups (p = 0.07). Multivariate analyses revealed that patients with more advanced disease status and raised LDH at ASCT independently predicted inferior DFS. There was one case of acute myeloid leukemia and two of prostate cancer, all of whom were in the TBI group. **Conclusions:** As compared to a BEAM based regimen, a 12 Gy TBI-based regimen resulted in a similar DFS. The TBI group had a trend toward poorer OS than a BEAM-based regimen that may accounted for by other confounding variables. There did not appear to be excess pulmonary or other acute toxicities in the TBI based group. Randomized controlled trials are required in order to establish the superiority of either regimen.

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HEMATOPOIETIC STEM CELL TRANSPLANTATION (SCT): A SINGLE CENTER EXPERIENCE IN COLOMBIA

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Here we report the results of autologous and allogenic SCT in a single institution in Bogotá, Colombia, between 1993 and 2007. We performed 532 SCT in 526 patients, 227 allogenic and 305 autologous.

In 294 (96.4%) of autologous-SCT, stem cells were obtained from peripheral blood. Mean $2.97 \times 10^6/\text{kg}$ (0.31–30) CD34+ cells, in 3 (1–8) apheresis, were collected. 224 (73.7%) were mobilized using Cyclofosfamide plus G-SCF. The rest were mobilized with various chemotherapy regimens or G-CSF alone. Indications for auto-SCT were: Non-Hodgkins Lymphoma 115, Hodgkin disease 93, multiple myeloma 59, solid tumors 18, acute leukemias 17, other 3. Mean age was 40.1 years (5–68). 189 (61.9%) were male. Most common conditioning regimens for lymphomas were BEAM and BEM. All MM patients were conditioned with Melphalan 200 mg/m². Hospitalization median time was 27 days (14–87). Day 100 TRM (transplant related mortality) was 6.23%. At mean 31.23 months (0.16–161) follow up overall and relapse free survival are 71% and 66.4% respectively. 60% of deaths were related to disease relapse.

Of 227 allo-SCT, in 214 SC were obtained from peripheral blood, only 13 were obtained from bone marrow. 153 (59%) were males. Most common indications for transplant were: Chronic myeloid leukemia 57, acute myeloid leukemia 46, acute lymphoid leukemia 41, bone marrow failure syndromes 44, Hodgkin's and non-Hodgkin lymphomas 14, MDS 9, other 12. Mean age was 30.1 (4–63) years. 72% of patients and 76% of donors were IgG CMV positive. Most common conditioning regimens for acute leukemias and lymphomas were BuCy, BuCy-etoposide, busulfan-fludarabine; and for aplastic anemia high dose cyclofosfamide or cyclophosphamide plus ATG. Hospitalization median time was 34 days (17–103). Day 100 TRM was 16.7%. At mean 25.72 months (0.27–147) follow up, overall and relapse free survival are 53.2% and 50.9% respectively.

Results described here are similar of ones reported in other centers around de world, they confirm that SCT is feasible in centers of developing world.

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PITUITARY APOPLEXY COMPLICATING AUTOLOGOUS STEM CELL TRANSPLANTATION

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Pituitary Apoplexy (PA) is an uncommon neurologic event that results from sudden hemorrhage or infarction of the pituitary gland. Most of these events occur in patients with undiagnosed pituitary adenoma. There are various precipitating causes. We report a case of PA precipitated by thrombocytopenia during autologous stem cell transplantation.

The patient is a 48M with history of stage II multiple myeloma initially treated with lenalidomide and dexamethasone. The patient then proceeded to Auto PSCT. His preparative regimen consisted of melphalan 200 mg/m². Initial lab values showed a platelet count of 429K/ul. The patient became febrile on Day 4 and was started on broad spectrum antibiotics. Voriconazole replaced fluconazole when fevers persisted. On Day 7, the patient complained of blurry vision. This was the first day plts were below 10K/ul. A possible culprit was voriconazole and it was discontinued. The patient complained his peripheral vision was particularly compromised, and bitemporal hemianopsia was confirmed. CT of the brain revealed a 2.3×2.5 cm hemorrhagic pituitary mass. Platelets were transfused to keep plts above 75K/ul. Hydrocortisone was begun, as was desmopressin, for developing diabetes insipidus. MRI confirmed a large suprasellar mass consistent with a pituitary macroadenoma that contained hemorrhage. The incidence of PA with pituitary adenoma is variable, but has been reported to be as high as 27.7%. Many patients have nonfunctional adenomas or are asymptomatic prior to the event. Clinical symptoms of PA are also variable but the most common symptoms include headache, nausea, and visual deficits. As in most cases, our patient had an undiagnosed pituitary adenoma and was asymptomatic. The thrombocytopenia and immunocompromise of PSCT can make the pituitary vulnerable to hemorrhage and abscess, both reported causes of apoplexy.